PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2008/001105	11.08.2008	13.08.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/053 A61B5/029 A61B5/083

Applicant
CHEETAH MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Görlach, Tobias Telephone No. +31 70 340-4214

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2008/001105

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-22,26,37-46

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-8,12-19,38,40-45
	No:	Claims	1,2,9-11,20-22,37,39,46
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-22,26,37-46
Industrial applicability (IA)	Yes:	Claims	1-22,26,37-46
	No:	Claims	

2. Citations and explanations

   see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV

Lack of unity of invention

1. Reference is made to the following document:

   D1: US 2005/004609 A1

2. This Authority considers that there are 2 inventions covered by the claims indicated as follows:

Ia:	Claims 3,12-17,38,40,41	directed to determining cardiovascular parameters;
Ib:	Claims 4-8	directed to body composition determination;
Ic:	Claim 46	directed to a system with skin electrodes;
Id:	Claims 18,19,42-45	directed to analog noise reduction;
II:	Claims 23-25,27-36	directed to setting frequency bounds for the adaptive filter.

2.1 The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

2.2 The closest prior art to the application as a whole has been identified as document D1 and discloses the features of claim 1 (the references in parentheses referring to D1):

A method of processing an input signal (118) pertaining to at least one electrical property of an organ of a subject (paragraph 27), comprising determining a physiological condition of the subject (paragraph 31), selecting a frequency band, filtering said signal according to said frequency band (paragraph 31), and dynamically adapting said frequency band in response to a change in said physiological condition, thereby processing the signal (paragraph 31).

(Note that while D1 does not disclose selecting a frequency band explicitely, the adaptive filter starts with some initial value, which amounts to selecting a frequency band.)

2.3 Document D1 also discloses all the features of claim 2:

A filtering device, comprising: a first input unit (112) for receiving an input pertaining to at least one electrical property of an organ of a subject, a second input unit (230,236) for receiving data pertaining to a physiological condition of the subject, and a filtering unit (226) configured for filtering said input signal according to a frequency band which is dynamically adapted in response to a change in said physiological condition (paragraph 31).

2.4 Document D1 also discloses all the features of claim 9 and, mutatis mutandis, of claim 20:

A method of monitoring at least one electrical property of an organ of a subject, comprising sensing an input radiofrequency signal from the organ (paragraph 27), processing said input radiofrequency signal to provide a processed input signal (paragraph 28), filtering said input signal using a dynamically variable filter to provide a filtered signal (paragraphs 30-31), and using said filtered signal for monitoring the at least one electrical property of the organ (paragraphs 26, 32, 33 and 47).

2.5 Furthermore, document D1 discloses the features of the following dependent claims:

- Claims 10,21: see D1, paragraph 31.
- Claim 11: see D1, paragraph 28, see also D2, column 12, line 45 - column 13, line 8.
- Claims 22,26: see D1, paragraph 31.
- Claim 37: see D1, paragraph 27.
- Claim 39: see D1, paragraph 28, see also D2, column 9, line 26 - column 13, line 8 and Figs. 4-6.

2.6 It follows that the following technical features of claims 3-8, 12, 18, 23, 27, 40, 42, 44 and 46, which are directly dependent on the claims whose subject-matter is disclosed in D1, make a contribution over the disclosures of document D1 and can be considered as special technical features (STF) within the meaning of Rule 13.2 PCT:

(note that although claim 13 is drafted as dependent on claim 9, it is in fact dependent on claim 12; see also the remarks under Item VIII).

- Claim 3: system for monitoring cardiac output;
- Claim 4: system for predicting BCM, FFM or TBW;
- Claim 5: system for determining hematocrit;
- Claim 6: system monitoring hydration status;
- Claim 7: system for discriminating tissue;
- Claim 8: system for calculating circumference of a body segment;
- Claims 12,40: calculating stroke volume, cardiac output or blood flow;
- Claims 18,44: mixing input and output RF signals;
- Claim 23: lower or upper frequency bound of filter vary linearly with heart rate;
- Claim 27: iteratively determined upper frequency bound of filter;
- Claim 38: hemodynamic reactance;
- Claim 42: envelope elimination unit;
- Claim 46: skin electrodes;

2.7 The problems solved by these special technical features can therefore be construed as:

- Claims 3,12,38,40: Determining cardiovascular parameters;
- Claims 4-8: Determining body composition;
- Claims 18,42,44: Analog noise reduction;
- Claims 23,27: setting frequency bounds for the adaptive filter;
- Claim 46: alternative measurement arrangement;

2.8 Grouping the STF by correspondence of technical effect, the following inventions can be distinguished:

1) Claims 3,12-17,38,40,41: means for determining cardiovascular parameters;
2) Claims 4-8: means for determining body composition;
3) Claims 18,19,42-45: analog noise reduction circuits;
4) Claims 23-25,27-36: criteria for adaptive filter frequency bounds.

5) Claim 46: skin electrodes;

2.9 Although inventions 1), 2) 3) and 5) are not so linked as to form a single general inventive concept (Rule 13.1 PCT), the effort involved in searching these four inventions does not justify an additional search fee. Therefore, inventions 1), 2), 3) and 5) have been searched.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US 2005/004609 A1 (STAHMANN JEFFREY E [US] ET AL) 6 January 2005 (2005-01-06)
D2: US-A-6 076 015 (HARTLEY JESSE W [US] ET AL) 13 June 2000 (2000-06-13)
D3: US-A-4 705 049 (JOHN ERWIN R [US]) 10 November 1987 (1987-11-10)
D4: RAZA S B ET AL: "FILTERING RESPIRATION AND LOW-FREQUENCY MOVEMENT ARTEFACTS FROM THE CARDIOGENIC ELECTRICAL IMPEDANCE SIGNAL" MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, SPRINGER, HEILDELBERG, DE, vol. 30, no. 5, 1 September 1992 (1992-09-01), pages 556-561, XP000323425 ISSN: 0140-0118
D5: KUBICEK W G ET AL: "THE MINNESOTA IMPEDANCE CARDIOGRAPH - THEORY AND APPLICATIONS" BIOMEDICAL ENGINEERING, UNITED TRADE PRESS, LONDON, GB, vol. 9, no. 9, 1 September 1974 (1974-09-01), pages 410-416, XP001051054 ISSN: 0006-2898
D6: US 2003/187341 A1 (SACKNER MARVIN A [US] ET AL) 2 October 2003 (2003-10-02)
D7: US 2004/133123 A1 (LEONHARDT STEFFEN [DE] ET AL) 8 July 2004 (2004-07-08)
D8: US 2004/102908 A1 (LARSON DENNIS E [US] ET AL) 27 May 2004 (2004-05-27)
D9: WO 2006/087696 A (NEW LEAF CAPITAL LTD [GB]; KEREN HANAN [IL];

SIMON AVRAM B [GB]) 24 August 2006 (2006-08-24) cited in the application

D10: US-A-5 615 689 (KOTLER DONALD P [US]) 1 April 1997 (1997-04-01) cited in the application

D11: US-A-5 642 734 (RUBEN PAUL [US] ET AL) 1 July 1997 (1997-07-01) cited in the application

D12: US 2003/120170 A1 (ZHU FANSAN [US] ET AL) 26 June 2003 (2003-06-26) cited in the application

D13: US 2006/085048 A1 (CORY PHILIP C [US] ET AL) 20 April 2006 (2006-04-20) cited in the application

2. The present application does not meet the criteria of the PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

2.1 The document D3 discloses (the references in parentheses applying to this document):

A method of processing an input signal pertaining to at least one electrical property of an organ of a subject (column 3, lines 26-41), comprising determining a physiological condition of the subject (column 6, lines 32-55; column 7, lines 21-48), selecting a frequency band (column 6, line 60 - column 7, line 2), filtering said signal according to said frequency band (column 7, lines 21-27), and dynamically adapting said frequency band in response to a change in said physiological condition, thereby processing the signal (column 7, lines 38-66).

2.2 The document D1 discloses (the references in parentheses applying to this document):

A method of processing an input signal (118) pertaining to at least one electrical property of an organ of a subject (paragraph 27), comprising determining a physiological condition of the subject (paragraph 31), selecting a frequency band, filtering said signal according to said frequency band (paragraph 31), and dynamically adapting said frequency band in response to a change in said physiological condition, thereby processing the signal (paragraph 31).

(Note that while D1 does not disclose selecting a frequency band explicitely, the adaptive filter starts with some initial value, which amounts to selecting a frequency band.)

2.3 The subject-matter of claim 1 is also disclosed in document D2, see column 9, line 26 - column 14, line 33 and Fig. 4; and in D4, see page 556, right column, paragraph 3 - page 557, right column, first paragraph; and in documents D6-D8, see the passages cited in the search report.

3. The present application does not meet the criteria of the PCT, because the subject-matter of claim 2 is not new in the sense of Article 33(2) PCT.

3.1 The document D1 discloses (the references in parentheses applying to this document):

A filtering device, comprising: a first input unit (112) for receiving an input pertaining to at least one electrical property of an organ of a subject, a second input unit (230,236) for receiving data pertaining to a physiological condition of the subject, and a filtering unit (226) configured for filtering said input signal according to a frequency band which is dynamically adapted in response to a change in said physiological condition (paragraph 31).

3.2 The document D6 discloses (the references in parentheses applying to this document):

A filtering device, comprising: a first input unit (205) for receiving an input pertaining to at least one electrical property of an organ of a subject, a second input unit (215) for receiving data pertaining to a physiological condition of the subject, and a filtering unit (220) configured for filtering said input signal according to a frequency band which is dynamically adapted in response to a change in said physiological condition (paragraph 44).

3.3 The subject-matter of claim 2 is also disclosed in document D2, see column 9, line 26

- column 14, line 33 and Figs. 1 and 4.

4. The present application does not meet the criteria of the PCT, because the subject-matter of claims 9 and 20 is not new in the sense of Article 33(2) PCT.

4.1 The document D1 discloses (the references in parentheses applying to this document):

A method of monitoring at least one electrical property of an organ of a subject, comprising sensing an input radiofrequency signal from the organ (paragraph 27), processing said input radiofrequency signal to provide a processed input signal (paragraph 28), filtering said input signal using a dynamically variable filter to provide a filtered signal (paragraphs 30-31), and using said filtered signal for monitoring the at least one electrical property of the organ (paragraphs 26, 32, 33 and 47).

(the details of the signal generation and processing are disclosed in document D2, column 6, line 14 - column 17, line 4, which is explicitely referenced by D1 and which also discloses the subject-matter of claim 9, see the passages cited in the search report).

4.2 The subject-matter of claim 9 is also disclosed in document D4, see page 557, left column, paragraph 3 - right column, first paragraph. For details on the impedance cardiograph used, see D5 (referenced by D4). The subject-matter of claim 9 is also disclosed in documents D7 and D8, see the passages cited in the search report.

4.3 The same reasoning applies, mutatis mutandis, to the subject-matter of claim 20, which therefore is also considered not new (Article 33(2) PCT).

5. Dependent claims 3-17,21,22,26,37-41 and 46 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step for the following reasons:

5.1 Novelty (Article 33(2) PCT):

- Claims 10,21: see D1, paragraph 31; see also D7, paragraph 25.
- Claim 11: see D1, paragraph 28, see also D2, column 12, line 45 - column 13, line 8.
- Claim 22: see D1, paragraph 31; and D4, page 557, left column, paragraph 3.
- Claim 26: see D1, paragraph 31; and D4, page 557, left column, paragraphs 3-4.
- Claim 37: see D1, paragraph 27.
- Claim 39: see D1, paragraph 28, see also D2, column 9, line 26 - column 13, line 8 and Figs. 4-6.
- Claim 46: see D4, page 557, left column, paragraph 4; see also D5, page 411, middle column, and Figs. 1 and 2; and D7, paragraphs 18-19 and Fig. 1.

5.2 Inventive Step (Article 33(3) PCT):

- Claim 3: see D9, page 23, lines 7-29.
- Claim 4: see D10, abstract.
- Claim 5: see D11, abstract.
- Claim 6: see D12, paragraphs 30-52.
- Claim 7: see D13, abstract.
- Claim 8: see D12, paragraphs 53-58.
- Claims 12,40: see D9, page 19, line 31 - page 20, line 18, page 26, lines 19-24, and page 29, lines 6-14; reference is also made to D5, page 412, middle column.
- Claim 13: see D9, page 26, line 26 - page 27, line 2.
- Claims 14,41: see D9, page 21, lines 3-9 and page 28, line 7 - page 29, line 5, and Fig. 2.
- Claim 15: see D1, paragraph 27 and Fig. 2; see also D2, column 6, line 50 - column 7, line 36.
- Claims 16,17,42,43: see D9, page 20, line 19 - page 21, line 2.
- Claims 18,19,44,45: see D9, page 21, line 10 - page 22, line 3 and Fig. 2.
- Claim 38: see D9, page 23, line 21 - page 24, line 3.

- Claim 46: see also D9, Figs. 4a-h.

Re Item VIII

Certain observations on the international application

1. Although claim 13 is drafted as dependent on claim 9, it is actually dependent on claim 12, because blood flow is not mentioned in claim 9.

2. In claim 11 and 39, the words "possessing" or "possessing unit" are used, although the intended meaning is probably "processing".

3. In claim 37, the word "of" is missing between "impedance" and "the organ".

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003